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**DEPARTMENT OF AGRICULTURE**

**Agricultural Marketing Service**

**7 CFR Part 205**

**[Document Number AMS-NOP-10-0083; NOP-10-09IR]**

RIN 0581-AD17

National Organic Program (NOP); Sunset Review (2012) for Nutrient Vitamins and Minerals

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Interim rule with request for comments.

**SUMMARY:** This interim rule addresses a recommendation submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on April 29, 2011.

This recommendation pertains to the 2012 Sunset Review for the exemption (use) of nutrient vitamins and minerals in organic handling on U.S. Department of Agriculture's (USDA)

National List of Allowed and Prohibited Substances (National List). On January 12, 2012, AMS published a proposed rule on the 2012 Sunset Review which proposed to continue the exemption (use) for nutrient vitamins and minerals on the National List for 5 years after its October 21, 2012 sunset date. The proposed rule also proposed to correct an inaccurate cross reference to U.S. Food and Drug Administration (FDA) regulations in the listing for vitamins and minerals on the National List. AMS continues to review the public comments on the proposed rule and assess the extent of impacts on the industry that could result from correcting the cross reference to FDA regulations. Therefore, due to the impending sunset of the allowance for nutrients vitamins and minerals from the National List on October 21, 2012, and based on the NOSB recommendation, this interim rule renews, without change, the exemption (use) for nutrient vitamins and minerals

on the National List. This interim rule provides for the continued use of nutrients vitamins and minerals in organic products until the agency completes the January 12, 2012, rulemaking.

**EFFECTIVE DATE:** This interim rule becomes effective October 21, 2012. All comments received by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered prior to the issuance of a final rule.

**ADDRESSES:** Interested persons may submit written comments on this interim rule using the following addresses:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Mail:** Toni Strother, Agricultural Marketing Specialist, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave., SW., Room 2646-So., Ag Stop 0268, Washington, DC 20250.

**Instructions:** All submissions received must include the docket number AMS-NOP-10-0083; NOP-10-09IR, and/or Regulatory Information Number (RIN) 0581-AD17 for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>. Comments submitted in response to this interim rule will also be available for viewing in person at USDA-AMS, National Organic Program, 1400 Independence Ave., SW, Room 2646-South Building, Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday, (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

**FOR FURTHER INFORMATION CONTACT:** Melissa Bailey, Ph.D., Director, Standards Division, Telephone: (202) 720-3252; Fax: (202) 205-7808.

**SUPPLEMENTARY INFORMATION:**

I. Background.

The Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501-6522), authorizes the establishment of the National List. The National List identifies synthetic substances that are exempted (allowed) in organic production and nonsynthetic substances that are prohibited in organic crop and livestock production. The National List also identifies nonagricultural nonsynthetic, nonagricultural synthetic and nonorganic agricultural substances that may be used in organic handling. The exemptions and prohibitions granted under the OFPA are required to be reviewed every 5 years by the National Organic Standards Board (NOSB). The Secretary has authority under the OFPA to renew such exemptions and prohibitions. If the substances are not reviewed by the NOSB within 5 years of their inclusion on the National List and addressed by the Secretary, then their authorized use or prohibition expires under OFPA's sunset provision.

On March 26, 2010, the National Organic Program (NOP) published an Advance Notice of Proposed Rulemaking (ANPR) to announce the pending sunset of substances on the National List and opened the public comment process on whether existing exemptions for specified synthetic and nonsynthetic substances in organic handling should be continued (75 FR 14500).<sup>1</sup> The ANPR indicated that the exemption for the use of nutrient vitamins and minerals as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" would expire after October 21, 2012, if the listing was not renewed. The public comment period lasted 60 days. Comments were received from organic

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<sup>1</sup> The Sunset 2012 ANPR also pertained to the exemptions for synthetic substances and prohibitions for nonsynthetic substances used in crop and livestock production.

handlers, ingredient suppliers and trade associations. Comments received supported the continued listing of nutrient vitamins and minerals in organic handling. The written comments can be retrieved at <http://www.regulations.gov> by searching for the document ID number: AMS-NOP-09-0074. The NOP provided the NOSB with these public comments to consider in their deliberations on the status of nutrient vitamins and minerals in organic products after the 2012 sunset date.

At their April 2011 public meeting, the NOSB approved a recommendation to renew the listing for nutrient vitamins and minerals after its October 21, 2012 sunset date. Their recommendation stated that the listing should be renewed as codified at 7 CFR 205.605(b): “Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods”.<sup>2</sup> In addition to the ANPR for Sunset 2012 published on March 26, 2010, the NOSB received additional public comment concerning the pending sunset of this listing in response to three Federal Register notices announcing meetings of the NOSB and its planned deliberations on recommendations involving Sunset 2012 substances. The notices were published in the Federal Register as follows: March 17, 2010 (75 FR 12723), September 20, 2010 (75 FR 57194), and March 4, 2011 (76 FR 12013). The NOSB received further written and oral testimony concerning nutrient vitamins and minerals at all three of these public business meetings which occurred in Woodland, CA on April 26 – 29, 2010, in Madison, WI on October 25 – 28, 2010, and in Seattle, WA on April 26 – 29, 2011. The written comments can be retrieved via <http://www.regulations.gov> by searching for the document ID numbers: AMS-NOP-10-0021 (May 2010 meeting); AMS-NOP-10-0068 (October 2010 meeting); and AMS-

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<sup>2</sup> NOSB, 2011, Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP), Nutrient Vitamins and Minerals Sunset, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5091724>

NOP-11-05 (April 2011 meeting). The oral comments were recorded in the meeting transcripts available on the NOP Web site, <http://www.ams.usda.gov/nop>.

During their April 2011 deliberations on the renewal of nutrients vitamins and minerals, the NOSB explained that the Food and Drug Administration (FDA) had recently provided a response to the NOP regarding the reference to 21 CFR 104.20 in the current annotation for nutrient vitamins and minerals on the National List.<sup>3</sup> The reference to 21 CFR 104.20 refers to the fortification policy for food under the FDA's jurisdiction. The NOP had requested the information from FDA to consider whether changes to the annotation were necessary to correct an inaccurate cross reference to FDA policy and to clarify what synthetic substances are allowed as vitamins and minerals in products labeled as "organic" or "made with organic (specified ingredients or food group(s))." The fortification policy at 21 CFR 104.20 provides for the rational addition of essential nutrients to food for human consumption. FDA considers only "essential nutrients" to be within the scope of its fortification policy at 21 CFR 104.20. The nutrients which FDA has determined to be essential are enumerated in 21 CFR 101.9(c)(8)(iv) with corresponding Reference Daily Intakes (RDIs), and 21 CFR 101.9(c)(9), which includes potassium and its corresponding Daily Reference Value (DRV). FDA stated that substances such as omega-3 and omega-6 fatty acids, inositol, choline, carnitine, and taurine are not essential nutrients listed under 101.9 (c)(8)(iv) and are, therefore, not within the scope of FDA's fortification policy at 21 CFR 104.20. The FDA also clarified that infant formula is not within the scope of the fortification policy; the requirements in 21 CFR part 107 pertain to required and essential nutrients for infant formula and include minimum and maximum amounts for those nutrients.

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<sup>3</sup> FDA Response to NOP - Questions and Answers Regarding Nutrient Fortification of Foods. April 14, 2011. Available at <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5090415>

Based on this information, the NOSB signaled its intent to issue another recommendation for an annotation change to the listing for nutrients vitamins and minerals at their November 2011 public meeting. However, since NOP intended to take action to amend the listing through a proposed rule, the NOSB opted to remove proposing a recommendation for an annotation change on nutrient vitamins and minerals from their November 2011 meeting agenda.

On January 12, 2012, AMS published a proposed rule on the 2012 Sunset Review for nutrient vitamins and minerals (77 FR 1980). The rule proposed to address the April 2011 NOSB recommendation and to revise the cross reference to FDA regulations to specify that only vitamins and minerals which are declared essential for food in 21 CFR 101.9 and vitamins and minerals that are required for infant formula in 21 CFR 107.10 and 107.100, may be used in organic products. As a result, under the proposal, any ingredient not specified by these cross references to FDA regulations would be excluded from use in organic products and would need to be petitioned to the NOSB for separate exemptions on the National List. Examples of affected ingredients which would need separate exemptions on the National List include docosahexanoic acid (DHA) algal oil, arachidonic acid (ARA) single-cell oil, taurine, inositol, choline, ascorbyl palmitate, synthetic beta-carotene, L-carnitine, lycopene, nucleotides, lutein, and L-methionine. Further, AMS would need to conduct separate rulemaking to codify the exemptions based on NOSB recommendations for any petitioned substances. A detailed discussion of the proposal, including further discussion of the examples of ingredients that would be affected and an initial assessment of the impacts of correcting the cross references to FDA regulations, is available in the proposed rule (77 FR 1980).

The proposed rule provided a 60 day comment period, which closed on March 12, 2012. Comments were specifically requested on: (i) the actual economic impacts of the proposed

action; (ii) the adequacy of the estimated impact of the proposed action on small entities; and (iii) the length of the proposed compliance date. AMS received 26 written comments in response to the proposed rule. The written comments can be retrieved via [www.regulations.gov](http://www.regulations.gov) by searching for the document ID number: AMS-NOP-10-0083. Persons wanting to visit the USDA South Building to view comments in response to the proposed rule are requested to make an appointment in advance by calling (202) 720-3252.

AMS continues to assess the public comments on the proposed rule and evaluate the impact of clarifying the cross reference to FDA regulations. Given that the current allowance for nutrient vitamins and minerals is due to sunset (“expire”) from the National List on October 21, 2012, AMS is issuing this interim rule with request for comments to provide continuity to the organic industry and avoid widespread disruption that would result if the allowance for vitamins and minerals were to sunset. For example, if the current allowance for vitamins and minerals was to sunset, Vitamins A and D, used to fortify fluid milk, and B-vitamins, used in bread and cereal to replace vitamins lost during processing, could no longer be added to organic products.

AMS believes that renewing the current listing for nutrient vitamins and minerals on the National List is the most appropriate action at this time. When AMS published the proposed rule in January 2012, the agency requested comments on the adequacy of the economic analysis that was presented and the two year compliance date that was proposed. AMS received limited public comment on the impacts of correcting the cross reference to FDA regulations. The NOSB has made final recommendations to AMS on four petitioned substances, petitions for eight substances remain outstanding. A summary of the status of these petitions is provided in Table 1.

Table 1. Status of National List Petitions for Affected Ingredients<sup>a</sup>

<b>Ingredient</b>	<b>Petition submitted to NOSB</b>	<b>NOSB Recommendation</b>
Docosahexanoic Acid (DHA) algal oil <sup>b</sup>	Yes.	NOSB recommended the addition to §205.605(a): DHA algal oil, not hexane extracted; other ingredients that are agricultural must be organic.
Arachidonic Acid (ARA) single-cell oil <sup>b</sup>	Yes.	NOSB recommended the addition to §205.605(a): Arachidonic Acid (ARA) from fungal oil, not hexane extracted; other ingredients that are agricultural must be organic.
Inositol	Yes	NOSB recommended the addition to § 205.605(b): CAS # 87-89-8 (myo-inositol) and 6917-35-7 (non-specific isomer) for use in infant formula and medical nutritional enteral products labeled organic or made with organic (specified ingredients or food group(s)).
Choline (two separate petitions for infant formula and infant food, and all other foods)	Yes.	NOSB recommended the addition to § 205.605(b): Choline chloride (CAS# 67-48-1) and Choline bitartrate (CAS # 87-67-2) for use in infant formula and medical nutritional enteral products labeled organic or made with organic (specified ingredients or food group(s)).
Ascorbyl Palmitate	Yes.	NOSB Handling Subcommittee proposal posted; NOSB Recommendation expected at October 2012 public meeting. <sup>c</sup>
Beta-carotene <sup>d</sup>	Yes.	NOSB Handling Subcommittee proposal posted; NOSB



		Recommendation expected at October 2012 public meeting.
L-carnitine	Yes.	NOSB Handling Subcommittee proposal posted; NOSB Recommendation expected at October 2012 public meeting.
Lycopene	Yes.	NOSB Handling Subcommittee proposal posted; NOSB Recommendation expected at October 2012 public meeting.
Lutein	Yes.	NOSB Handling Subcommittee proposal posted; NOSB Recommendation expected at October 2012 public meeting.
L-Methionine	Yes.	NOSB Handling Subcommittee proposal posted; NOSB Recommendation expected at October 2012 public meeting.
Nucleotides	Yes.	NOSB Handling Subcommittee proposal posted; NOSB Recommendation expected at October 2012 public meeting.
Taurine	Yes.	NOSB Handling Subcommittee proposal posted; NOSB Recommendation expected at October 2012 public meeting.
Amino Acids for pet food	Yes.	NOSB Livestock Subcommittee proposal posted; NOSB Recommendation expected at October 2012 public meeting.

<sup>a</sup> Petitions are available on the NOP website in the petitioned substances database:

<http://www.ams.usda.gov/NOPNationalList>.

<sup>b</sup> Some of the DHA and ARA used in organic products is derived from fish oil, currently provided for in section 205.606 of the National List, rather than algal and microbial sources.

<sup>c</sup> All NOSB subcommittee proposals are available online at

<http://www.ams.usda.gov/NOSBCommitteeRecommendations> . Information for the October 15-18, 2012 NOSB public meeting is available online at <http://www.ams.usda.gov/NOSBMeetings>.

<sup>d</sup> The beta-carotene petition is for the synthetic form. Beta-carotene extract color is currently listed in section 205.606 as a nonorganically produced agricultural ingredient allowed in products labeled “organic” when an organic version is not commercially available.

Once the NOSB completes its review and has issued recommendations on all petitioned nutrients, the public will be able to more fully comment on the implications of correcting the FDA cross reference as proposed. For this reason, we are requesting comments through this interim rule. After consideration of comments submitted to both the proposed rule and this interim rule, AMS intends to issue a final rule that will address the proposed correction to the listing for nutrient vitamins and minerals on the National List. As previously noted, AMS would need to conduct separate rulemaking to codify the exemptions based on recommendations by the NOSB for any petitioned substance.

Therefore, consistent with the April 2011 NOSB recommendation, this interim rule continues the allowance for nutrient vitamins and minerals at section 205.605(b) as follows: “Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods.” This action enables the industry to continue with the status quo until additional public comments are received and a final rule is published. This action avoids the widespread disruption to the organic market that would occur if the allowance for any synthetic vitamins and minerals were to sunset (“expire”) from the National List on October 21, 2012.

## II. Statutory and Regulatory Authority

The OFPA authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The

National List petition process is implemented under section 205.607 of the NOP regulations. The current petition process (72 FR 2167, January 18, 2007) can be accessed through the NOP Website at <http://www.ams.usda.gov>.

A. Executive Order 12866.

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

B. Executive Order 12988.

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This interim rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in the OFPA (7 U.S.C. 6514(b)). States are also preempted by the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA,

(c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to the OFPA (7 U.S.C. 6519(f)), this interim rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 - 624), the Poultry Products Inspection Act (21 U.S.C. 451 - 471), or the Egg Products Inspection Act (21 U.S.C. 1031 - 1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 - 399), nor the authority of the Administrator of EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)(7 U.S.C. 136 – 136(y)).

The OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's final decision.

### C. Regulatory Flexibility Act.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small business will not be unduly or disproportionately burdened. Section 605 of the RFA allows an agency to

certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, AMS performed an economic impact analysis on small entities in the final rule published in the Federal Register on December 21, 2000 (65 FR 80548). AMS has also considered the economic impact of this interim rule on small entities. The effect of this rule would be to allow the continued use of nutrients vitamins and minerals in organic handling. AMS concludes that the economic impact of continuing this allowance for nutrient vitamins and minerals in organic handling would avoid market disruption and would be beneficial to small agricultural service firms. Therefore, AMS certifies that this rule would not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$7,000,000 and small agricultural producers are defined as those having annual receipts of less than \$750,000.

Based on USDA data from the Economic Research Service (ERS), the total acreage of certified organic land grew from 1.8 million acres in 2000 to 4.8 million acres in 2008, of which approximately 2.2 million acres was pasture and rangeland.<sup>4</sup> The number of certified organic producers in the U.S. has more than doubled in that time period rising from approximately 7,000 in 2000 to nearly 17,700 by the end of 2011.<sup>5</sup> ERS, based upon the list of certified operations maintained by the NOP, estimated the number of certified handling operations was 3,225 in

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<sup>4</sup> U.S. Department of Agriculture, Economic Research Service. 2008. *U.S. Organic Agriculture, 1992-2008*, data set, available at [www.ers.usda.gov/data/organicERS](http://www.ers.usda.gov/data/organicERS). The number of U.S. organic operations at the end of 2011 is from data compiled by the National Organic Program, <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5097523>.

<sup>5</sup> Ibid.

2007. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

The increasing production capacity for organic agricultural products parallels growth trends in sales of organic products. Since implementation of the NOP, the organic industry has experienced consecutive years of growth demonstrated by increasing sales to consumers. In 2011, U.S. retail sales of organic food and beverages totaled over \$29.2 billion.<sup>6</sup> The pace of double-digit sales growth that persisted from 2002-2008 has dipped, but the 7.7 percent growth recorded from 2009-2010, and the 9.4 percent growth recorded from 2010-2011, marked increases from previous years. The top grossing organic food categories in terms of sales for 2011 are fruits and vegetables (40.5%), dairy (14.6%) and packaged/prepared foods, which includes baby formula and baby food (13.6%). Sales of dry breakfast goods, which includes cereals, grew 6.2% in the year 2011, exceeding \$1 billion. Organic frozen prepared foods account for the highest sales within the packaged/prepared foods category. Nutrient vitamins and minerals are used to fortify products in the dairy, packaged/prepared foods, and breakfast goods product categories.

In addition, USDA has 91 accredited certifying agents who provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP web site, at <http://www.ams.usda.gov/nop>. AMS believes that most of these accredited certifying agents would be considered small entities under the criteria established by the SBA.

#### D. Paperwork Reduction Act.

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<sup>6</sup> Organic Trade Association, 2012. *2012 Organic Industry Survey*. Brattleboro, VT.

No additional collection or recordkeeping requirements are imposed on the public by this interim rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

E. Executive Order 13175.

This interim rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

F. Effective Date.

This interim rule reflects a recommendation submitted to the Secretary by the NOSB for the purpose of fulfilling the requirements of 7 U.S.C. 6517(e) of the OFPA. Section 7 U.S.C. 6517(e) requires the NOSB to review each substance on the National List within 5 years of its publication. Pursuant to 5 U.S.C. 553, it is found and determined upon good cause that it is impracticable and contrary to the public interest to give preliminary notice prior to putting this rule into effect in order to ensure the continued use of nutrients vitamins and minerals in organic products after October 21, 2012, and avoid widespread disruption to the organic market. Accordingly, this rule shall be effective on October 21, 2012.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and

recordkeeping requirements, Seals and insignia, Soil conservation.

The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501-6522.

Dated: September 21, 2012

David R. Shipman  
Administrator  
Agricultural Marketing Service

[FR Doc. 2012-23748 Filed 09/26/2012 at 8:45 am; Publication Date: 09/27/2012]